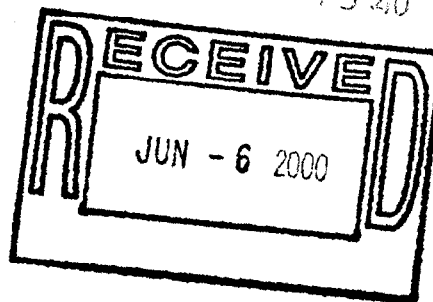




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May 31, 2000

The Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C. Street S.W.
Washington, DC 20204

Dear Sir/Madam:

This is a notification pursuant to 21 U.S.C. 343(r)(6) that Standard Process Inc., Palmyra, Wisconsin 53156-0904, is making the following statements:

- (1) Bovine brain tissues like the pineal, hypothalamus, and pituitary, are combined with bovine liver and spleen in Neuroplex, to provide concentrated nutrients that are especially supportive to their parallel tissues in the human body. Vitamins and minerals contained in Neuroplex enable enzymes and hormones to function properly, contributing to the healthy maintenance of the nervous, endocrine, and immune systems, as well as other control functions for the body.
- (2) Neuroplex promotes healthy endocrine and nervous system functions.
- (3) Melatonin plays a critical role to the body's biological clock, causing induction of sleep through its influence on circadian rhythms. Since melatonin passes through all cell membranes, all cells receive the information that regulates the body's biological clock.
- (4) Thiamin influences mental attitude and is related to maintaining a healthy nervous system. It enhances cognitive activity and brain function. Vitamin B6 plays a predominant role in metabolic processes in the central nervous system and is necessary for normal brain function. It also helps regulate water balance throughout the body. Riboflavin (Vitamin B2) enhances the effectiveness of the thyroid hormone and is involved in adrenal gland function. Niacin is important for normal nervous system function and also synthesizes the sex hormones.
- (5) Neuroplex maintains cellular health.

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- (6) Zinc, copper and riboflavin support the immune system's antibody function. Vitamin B6 is required for DNA and RNA synthesis. Thiamin plays a vital role in energy release for all cells during carbohydrate metabolism.
- (7) Neuroplex supports enzyme function.
- (8) Riboflavin combines with a number of substances and proteins to produce coenzymes essential to cell metabolic functions. Vitamin B6 acts as a co-enzyme with other enzymes involved in cell growth and division. All cells depend upon iron to complete oxygen exchange because of its role in the function of most cell enzymes. Zinc and copper are essential to the structure and function of many enzymes. Copper-containing enzymes form a number of brain nerve transmitters.
- (9) Contains a distinctive combination of anterior pituitary, hypothalamus, pineal, brain PMG extract™, and orchic Cytosol extract™ which is beneficial for stimulation and support of the healthy function of these tissues.
- (10) Protomorphogen™ extracts and glandular tissues support the corresponding organs in humans.

These statements are made for a dietary supplement containing a proprietary blend of *Tillandsia usneoides*, bovine orchic Cytosol™ extract, bovine spleen, bovine brain PMG™ extract, defatted wheat (germ), bovine hypothalamus, bovine anterior pituitary, calcium lactate, bovine liver, potassium para-aminobenzoate, bovine pituitary PMG™ extract, bovine brain, and ascorbic acid. Other ingredients include gelatin, zinc liver chelate, iron liver chelate, niacinamide, water, pyridoxine hydrochloride, calcium stearate, natural colors, copper liver chelate, cocarboxylase, and riboflavin. The name of the product is Neuroplex®.

The information contained herein is accurate and Standard Process Inc. has substantiation that the statements are truthful and not misleading.

Sincerely yours,

Ann Holden
Standard Process Inc.

